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510 (k) Summary DEC 14 2005

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: December 6, 2005

Applicant: Nexa Orthopedics, Inc., (dba Futura Biomedical, LLC)
10675 Sorrento Valley Road, Suite 100
San Diego, CA 92121

Telephone: 858-866-0660
Fax: 858-866-0661
Contact: Louise M. Focht

Device Name:	Nexa bone screw system
Device Trade Name:	Nexa bone screw system
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3040
Product Code:	87 HWC
Predicate Device:	K043583 – Charlotte Snap-off Screw System
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description:

The Nexa Orthopedics bone screw system consists of screws made of Titanium (6AL-4V ELI) intended to be implanted into the bones of the foot, and hand. The screws are provided in 6 sizes. The screws are used for fixation of fractures, fusions, or osteotomies of bones of the hand and foot. The design of the Nexa bone screw system is similar in shape and size to the Wright Medical Charlotte Snap-Off Screw. No new materials are used in the development of this implant.

Indications for Use:

The Nexa bone screw system provides fixation of fractures, fusions, or osteotomies of bones of the hand and foot.

Comparison to Predicate Device:

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The legally marketed predicate device to which this device is substantially equivalent is the Wright Medical Charlotte Snap-Off Screw

Regulatory Class: II
Product Code: 87 HWC

Table 1. Comparison of Nexa Orthopedics and Wright Medical Snap off screw.

Item	*Nexa Orthopedics*	*Wright Medical*
Product Name	Nexa bone screw system	Charlotte Snap-Off Screw
Use	Single use	Single use
Fixation	Screw	Screw
Material	Titanium 6AL-4V ELI	Titanium alloy 6AL-4V
Sizes	6 sizes	3 sizes
Indications for use	The Nexa bone screw system provides fixation for fractures, fusions, or osteotomies of bones of the hand and foot.	The Charlotte Snap Off Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include: Fixation of Small Bone Fragments Weil osteotomy Mono-cortical fixation Osteotomies and fractures fixation in the foot and hand.

Similarities of the Nexa Orthopedics bone screw system and Wright Medical Snap-Off Screw include:

Both devices are: intended for single use only; intended for surgical implantation longer than 30 days; both devices are screws for fixation of fractures, fusions, or osteotomies, of bones of the hand and foot; both devices are made of industry standard materials, no new materials are introduced in either product; Both devices are comparably sized; both devices have the same indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2005

Mr. Louise M. Focht
Nexa Orthopedics, Inc.,
10675 Sorrento Valley Road, Suite 100
San Diego, California 92121

Re: K053394
Trade/Device Name: Nexa bone screw system
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: II
Product Code: HWC
Dated: December 5, 2005
Received: December 6, 2005

Dear Mr. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (If Known): K053394
Device Name: Nexa bone plate and screw system

Indications for Use:

The Nexa bone screw system provides fixation of fractures, fusions, or osteotomies of bones of the hand and foot.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, Res
and Neurological Device

510(k) Number K053394